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| APPLICATION NO.         | FILING DATE                 | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO.     |  |
|-------------------------|-----------------------------|----------------------|-------------------------|----------------------|--|
| 10/612,144              | 07/02/2003                  | Arjan Tibbe          | CT Imaging              | 3349                 |  |
| 40541                   | 7590 06/14/2006             |                      | EXAM                    | INER                 |  |
| IMMUNICON CORPORATION   |                             |                      | LEVKOVICH,              | LEVKOVICH, NATALIA A |  |
| 3401 MASON<br>SUITE 100 | S MILL ROAD                 |                      | ART UNIT                | PAPER NUMBER         |  |
| HUNTINGDO               | HUNTINGDON VALLEY, PA 19006 |                      |                         |                      |  |
|                         |                             |                      | DATE MAILED: 06/14/2006 |                      |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.  | Applicant(s)  |  |  |  |
|--|--|---|--|--|--|
|  | 10/612,144   | TIBBE ET AL.  |  |  |  |
| Office Action Summary  | Examiner   | Art Unit  |  |  |  |
|  | Natalia Levkovich  | 1743  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply   |  |   |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period was realiure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).                             | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONEI | l. ely filed the mailing date of this communication. O (35 U.S.C. § 133). |  |  |  |
| Status   |  |   |  |  |  |
| <ul> <li>1) ⊠ Responsive to communication(s) filed on 23 March 2006.</li> <li>2a) ☐ This action is FINAL.</li> <li>2b) ☒ This action is non-final.</li> <li>3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.</li> </ul>  |  |   |  |  |  |
| Disposition of Claims  |  |   |  |  |  |
| 4)  Claim(s) 1-25 is/are pending in the application. 4a) Of the above claim(s) 1-7 and 11-20 is/are versions.  5)  Claim(s) is/are allowed.  6)  Claim(s) 8-10 and 21-24 is/are rejected.  7)  Claim(s) 25 is/are objected to.  8)  Claim(s) 1-25 are subject to restriction and/or expressions.   | withdrawn from consideration.  |   |  |  |  |
| Application Papers   |  |   |  |  |  |
| 9) The specification is objected to by the Examiner 10) The drawing(s) filed on <u>02 July 2003</u> is/are: a) Applicant may not request that any objection to the of Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examiner  | $\square$ accepted or b) $\boxtimes$ objected to b drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj                                      | 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).                         |  |  |  |
| Priority under 35 U.S.C. § 119   |  |   |  |  |  |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  a) All b) Some * c) None of:  1. Certified copies of the priority documents have been received.  2. Certified copies of the priority documents have been received in Application No.  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received. |  |   |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date   | 4) Interview Summary ( Paper No(s)/Mail Da 5) Notice of Informal Pa  |   |  |  |  |

#### **DETAILED ACTION**

### **Drawings**

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the 'sample chamber with a collection surface' and the nickel lines must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filling date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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### Claim Objection

2. Claim 25 is objected because of wrong dependency, since a method claim cannot depend on an apparatus claim.

## Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 21-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the specification does not describe the dichroic mirror and the means for merging sub-images recited in claim 21.

## Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 6. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
  - 1. Determining the scope and contents of the prior art.
  - 2. Ascertaining the differences between the prior art and the claims at issue.
  - 3. Resolving the level of ordinary skill in the pertinent art.
  - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 7. Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leblans et al. (US 20040069857) in view of Crandall et al. (US 20040252875).

Leblans discloses a "microcarrier manipulation and identification apparatus" comprising a sample chamber, magnets, a laser as a light source, CCD cameras, a computer "for monitoring" the assay and means for amplifying the signal such as a photomultiplier tube or other light detector "capable of detecting the presence, location, intensity, excitation and emission spectra, fluorescence polarization, fluorescence lifetime, and other physical properties of the fluorescent signal" (Abstract; Figures 1 and 3; [0069], [0118], [0072], [0077], [0086], [0087]). The magnetic field caused by the magnets "holds the microcarrier ['magnetically labeled target entities' – Ex.] into place and orients it at the same time... Two coils are provided that can induce a magnetic field parallel to the capillary. Outside the magnetic field, the carriers will rotate because of the friction of the fluid. Inside the coils, the magnetic field will try to align the dipole momentum ... thus

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eliminating the rotation in the direction of the movement of the particle" ([0090], [0091]; Figures 1-2).

Leblans does not teach the computer configured to recombine sub-images of the particles into a 'complete image', such method of image reconstruction is well known. For example, Crandall discloses a data management system configured for "processing, storing, and viewing theextremely large imagery data ... produced by a linear-array-based microscope slide scanner ... The data are received as a series of overlapping image stripes ['sub-images' – Ex.] and combined into a seamless and contiguous baseline image. The baseline image is logically mapped into a plurality of regions that are individually addressed to facilitate viewing and manipulation of the baseline image" (Abstract). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have configured the computer in the modified apparatus of Leblans in the above described manner, in order to increase the resolution and facilitate viewing and manipulation of the images.

# Allowable Subject Matter

8. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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The prior art does not teach, or fairly suggest an apparatus for analytical imaging of target entities comprising an arrangement of magnets in combination with nickel stripes arranged on a substrate to align the entities, as recited in clam 9.

#### Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

Wohlstadter et al. (US 20050052646) – discloses beam splitters, mirrors and lenses

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462. The examiner can normally be reached on Mon-Fri, 8 a.m.-4p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 571-273-8300 (toll-free).

upervisory Patent Examinel Technology Center 1700